







## Incidents and adverse events notified at hospital level\*

### Incidentes e eventos adversos notificados em âmbito hospitalar

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 Andréia Mascarello<sup>1</sup>  
 Aline Massaroli<sup>1</sup>  
 Erica de Brito Pitilin<sup>1</sup>  
 Jeferson Santos Araújo<sup>1</sup>  
 Maria Eduarda Rodrigues<sup>1</sup>  
 Jeane Barros de Souza<sup>1</sup>

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<sup>1</sup>Universidade Federal da Fronteira Sul.  
Chapecó, SC, Brazil.

#### Corresponding author:

Andreia Mascarello  
Rua Altair Bacin, 20 D, Villa Real,  
CEP: 89805-875. Chapecó, SC, Brazil.  
E-mail: [deiamasca9@gmail.com](mailto:deiamasca9@gmail.com)

EDITOR IN CHIEF: Ana Fatima Carvalho Fernandes  
ASSOCIATE EDITOR: Renan Alves Silva

#### ABSTRACT

**Objective:** to identify the incidents and adverse events notified in a large size hospital. **Methods:** a retrospective study was carried out based on data extracted from handwritten notifications sheets, made available by the Patient Safety Nucleus of a large size hospital. The following variables were analyzed: type of incident, according to international safety goals; severity of the incidents with damage; and measures proposed to minimize the effects of the notified incident. **Results:** among the 1167 notifications, 653 (66.8%) of the incidents were related to pharmacovigilance, 563 (48.6%) presented as potential harm, 355 (28.7%) caused harm to the patient and of these, 228 (68.0%) were of mild intensity. Proposed actions were described in 705 (60.4%) of the notifications. **Conclusion:** the notifications allowed identifying a high number of incidents with potential to cause harm, denoting failures that could be minimized with the implementation of institutional protocols and professional training.

**Descriptors:** Patient Safety; Notification; Delivery of Health Care.

#### RESUMO

**Objetivo:** identificar os incidentes e eventos adversos notificados em um hospital de grande porte. **Métodos:** estudo retrospectivo, realizado com base em dados extraídos das fichas de notificações manuscritas, disponibilizados pelo Núcleo de Segurança do paciente de um hospital de grande porte. Analisaram-se as seguintes variáveis: tipo de incidente, conforme as metas internacionais de segurança; gravidade dos incidentes com dano; e medidas propostas para minimizar os efeitos do incidente notificado. **Resultados:** entre as 1167 notificações, 653 (66,8%) dos incidentes estavam relacionados com farmacovigilância, 563 (48,6%) apresentavam-se como potencial dano, 355 (28,7%) ocasionaram dano ao paciente e destes, 228 (68,0%) foram de intensidade leve. Ações propostas estavam descritas em 705 (60,4%) das notificações. **Conclusão:** as notificações permitiram identificar um elevado número de incidentes com potencial para causar dano, denotando falhas passíveis de serem minimizadas com a implantação de protocolos institucionais e capacitação profissional.

**Descritores:** Segurança do Paciente; Notificação; Assistência à Saúde.

## Introduction

The health systems are worried about procedures performed, in an inadequate way, when they find high rates of incidents occurred in the various care processes. Therefore, to ensure effective patient care, quality and safety are essential attributes, since the population looks for these services to recover or improve their health, without the expectation of suffering any kind of damage due to the care received, and also related to reasons that could be avoided<sup>(1)</sup>.

An incident is called an event or conjuncture originating from the care, which has no congruence with the existing pathology. Incidents are categorized into: incident with harm, also called adverse event, when it causes some type of harm or negative consequence to the patient, being able to cause his death; incident without harm, when it reaches the patient and does not result in harm, these, although not requiring additional interventions, constitute a threat to health; potential harm (near-miss) is the incident identified and intercepted before reaching the patient; and notifiable circumstance is that recognized as an event with high capacity to cause harm, however the event does not occur<sup>(2)</sup>.

Thus, notification is a useful tool to know, analyze and predict any type of incident, which, when inserted in the routine, allows the proper management of system failures, being considered an efficient tool to improve the quality of health care, since it allows the identification of the types of errors and risks that often occur during care and that can compromise the safety of patients<sup>(3-4)</sup>.

The consequences of possible wrong events cause unfavorable repercussions for patients and their families and for society and health systems. The fatality of the adverse event in the execution of the care to hospitalized patients fosters complications in the re-establishment of their health, with an increase in hospital infection rates, in the estimated length of hospitalization and financial costs<sup>(4-5)</sup>. It is estimated that between four and ten hospital admissions result in the occurrence of at least one adverse event, alar-

ming data that call attention, considering that half of these incidents could have been avoided<sup>(5-6)</sup>.

In addition, the costs incurred for treatment and minimization of the effects caused by adverse events could be reversed in actions to improve the quality and safety of health systems. Regarding financial costs and length of stay related to adverse events, a study has identified that length of stay increases around 28.3 days in relation to the usual length of stay, and treatment costs increase by 200.5%<sup>(6)</sup>.

In this context, this study is based on the assumption that errors can bring damage and adverse effects, but can also be used as tools for learning and development of an organization, based on the critical analysis of the notifications to verify and control the possibility of hazards and collaborate with the investigation of possibilities to clarify obstacles regarding the care.

This research will contribute as a tool to assist the management of care for the early recognition of the risks to which patients are vulnerable in institutions. Based on these findings, health professionals will be able to develop preventive measures aimed at making assistance safer and stimulating corrective actions aimed at not repeating errors and preventing risks and improving the quality of care.

In view of the above, this study aimed to identify the adverse incidents and events reported in a large size hospital.

## Methods

This is a retrospective study based on data extracted from incident and/or adverse event notification forms in a large hospital in the South of Brazil, with approximately 300 beds, a reference in oncological care, traumatology, transplantation and high-risk pregnancy. The institution established the Patient Safety Nucleus in 2013, composed of a multidisciplinary committee with representatives from all sectors of the hospital.

Data collection took place between February and April 2019. In total, 1191 records were analyzed

and of these, 1167 notifications were included in the period from January 1, 2017 to December 31, 2018, because it was during this period that the records began to be filed in the institution's database. Twenty-four records were excluded because they were illegible or incomplete.

To collect and organize data, the program Microsoft Office Excel® 2018 was used, performing the process of double typing and subsequent validation. The instrument contained the information from the notification form, namely: notification date; notification sector; incident category (medication, blood components, equipment, medical articles, vaccines); incident description; description of additional information; and referrals.

The data extracted from the notifications were classified following the definitions of the *International Classification for Patient Safety* (ICPS) of the World Health Organization. Notifications were also classified according to the type of incident: notifiable circumstance (with potential to cause harm or injury); potential for harm or near-miss (did not reach the patient); incident without harm (the incident reached the patient but did not cause harm); and adverse event (resulted in harm to the patient)<sup>(7)</sup>.

The incidents that caused harm to the patient (adverse event) were classified according to the degree of harm: Degree I (mild): minimal harm with a short interval of time and merely derisory interferences; Degree II (moderate): presents symptoms and needs interference from health professionals,

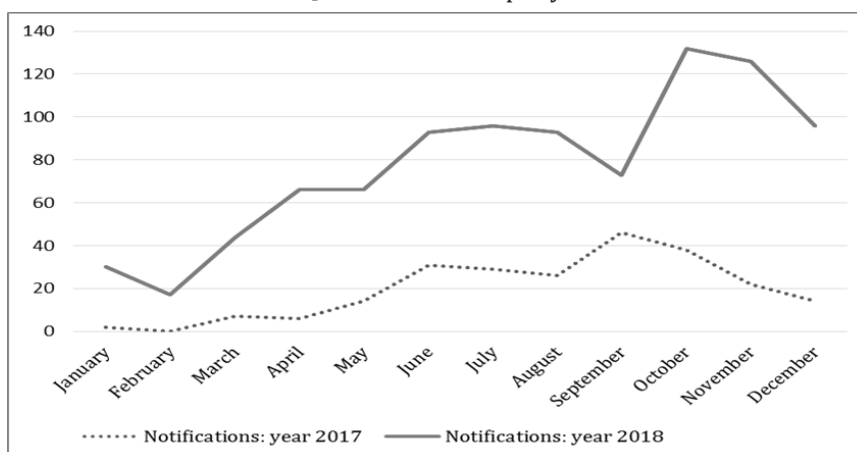
with increased period of hospitalization and harm or absence of definitive functionality or for an extended period; Degree III (severe): requires arrangements for the set of measures and procedures of life support or surgical execution of large size, causing reduction in survival, with absence of definitive functionality or for an extended period. Degree IV (death): the incident hastened or caused death<sup>(7)</sup>.

Information was collected on the measures proposed by the Patient Safety Nucleus to minimize the recorded incident and to avoid new occurrences of non-conformities. For analysis, descriptive statistics were used, and the results were presented by means of tables and graphs.

This investigation is an excerpt of a research macro-project, entitled Patient Safety: building pathways for the culture of safety, which was approved by the Committee of Ethics and Research with Human Beings by the opinion No. 2,621,561/2018 and Certificate of Presentation of Ethical Appreciation No. 85960518.0.0000.5564, according to the norms of Resolution No. 466/12 of the National Health Council of the Ministry of Health.

## Results

In the study period, 1,167 notifications of related patient safety incidents were received with a mean of 48.6 notifications/month (standard deviation (SD)  $\pm 38.9$ ). Figure 1 shows the mean notifications per year.



**Figure 1** – Number of notifications of incidents and/or adverse events related to patient safety from January 2017 to December 2018. Chapecó, SC, Brazil, 2019

There was a significant increase in the number of notifications, which coincided with the period of activities of the extension program in the hospital that worked on safety goals and emphasized the importance of notification with the more intense action of the Patient Safety Nucleus in actions related to the subject in the institution. There is a decrease in notifications in the months of October and December, probably related to the professionals' vacation period and a decrease in the number of attendances.

Of the incidents reported from January to December 2017, the main reasons were hyperemia/phlebitis (54.5%), fall (27.2%), infection related to health care (4.5%), and infiltration and extravasation of solution through the subcutaneous tissue with the same incidence.

In 2018, these were identification errors (30.1%), hyperemia/phlebitis (26.0%) and fall (14.8%). In 2017, 3 (1.3%) incidents with blood components were reported in relation to the total index for the same year and 43 (4.6%) in 2018 and in both the main cause was related to transfusion reaction. Still in 2017, 10 (4.3%) incidents were related to medical-hospital articles and 6 (2.6%) to equipment problems. In 2018, 109 (11.7%) medical-hospital articles and 8 (0.9%) problems with equipment were reported.

Regarding pharmacovigilance in the year 2017, the incidence of errors related to prescriptions (46.0%), dispensing (19.3%) and administration (16.6%) were highlighted. While in 2018, dispensing (36.7%), prescriptions (28.4%) and others (12.7%) stood out, interpreted in this study as those incidents with drugs that do not fit the descriptions above.

Table 1 presents the classification of the reported incidents according to the patient safety goals in the study period, corresponding to 977 (82.0%) of the total notifications. The remaining notifications were related to technovigilance and hemovigilance, that is, outside the goal classification items. Among the six

international goals for patient safety analyzed, it was decided to divide the "Goal 6: reduce the risk of falls and pressure injuries" in order to obtain better indicators for evaluation in the study.

**Table 1** – Incident notifications according to patient safety goals regarding the years under study. Chapecó, SC, Brazil, 2019

Patient safety goals	2017	2018	Total
	n (%)	n (%)	n (%)
Correct patient identification	7 (7.8)	82 (92.1)	89 (9.1)
Effective communication	-	24 (100.0)	24 (2.4)
Improve drug safety	150 (22.9)	503 (77.0)	653 (66.8)
Safe Surgery	3 (60)	2 (40.0)	5 (0.5)
Reduce the risk of infection	46 (31.7)	99 (68.2)	145 (14.8)
Reduce the risk of damage from falls	18 (30.5)	41 (69.4)	59 (6.0)
Reduce the risk of pressure injury	-	2 (100.0)	2 (0.2)

Problems were identified as prevalent in relation to the goals, such as in the "Correct identification of the patient", failure in the identification bracelet, 81 (91.0%); in the "Effective communication", the occurrence of information failure among professionals, in 24 (100.0%) of the cases analyzed; as well as in the "Safe Surgery", where technical failures prevail during the procedures performed, 5 (100.0%).

In the goal "Improve drug safety", incidents related to prescriptions, 300 (46.0%), dispensing, 126 (19.3%) and administration, 109 (16.7%) were highlighted. It was observed that the goal "Reduce the risk of infection" was related to scarcity of aseptic procedures, 99(68%), and the prevalence of falls was due to loss of balance, 32 (54.2%), slipping, 23 (38.9%) and syncope, 4 (6.7%). In "Reducing the risk of injury by pressure", the highlight was for injury resulting from surgical positioning, 2 (100.0%).

Table 2 shows the classification of the notifications as to type of incident and degree of harm.

**Table 2** – Classification of notifications according to the type of incident and degree of harm of adverse events according to the years under study. Chapecó, SC, Brazil, 2019

Type of incident	2017	2018	Total
	n (%)	n (%)	n (%)
Notifiable Circumstance	10 (6.1)	152 (93.8)	162 (14.0)
Potential harm	83 (14.7)	480 (85.2)	563 (48.0)
Incident without harm	17 (48.5)	18 (51.4)	35 (3.0)
Adverse Event	64 (19.1)	271 (80.8)	335 (29.0)
It was not possible to identify	61 (84.7)	11 (15.27)	72 (6.0)
Degree of harm from adverse events			
Take	44 (19.2)	184 (80.7)	228 (68.0)
Moderated	4 (10.5)	34 (89.4)	38 (11.0)
Record	1 (33.3)	2 (66.6)	3 (1.0)
Death	-	-	-
Unclassified*	15 (22.7)	51 (77.2)	66 (20.0)

\*Due to the lack of information in the notification form, it was not possible to conclude what was the degree of damage caused by the adverse event

In the incidents classified as notifiable, the problems related to Medical Devices/Equipment were highlighted, 9 (90.0%) in the year 2017, followed by 130 (85.5%) in the year 2018. Regarding incidents with potential harm, the highest rate was directed to the medical process, totaling 60 cases (72.2%) in 2017 and 400 (83.3%) in 2018. In the incidents without harm, there was prevalence of falls, 10 cases (58.8%) in 2017 and 15 (83.3%) in 2018.

Regarding the analysis of the actions proposed to minimize the effects of the notified incident, considering that this information was recorded in 705 (60.4%) of the files analyzed, during the year 2017, the following measures were highlighted: request to change the prescription, 21 (9.3%); carrying out training, 20 (8.9%); carrying out intervention to minimize the incident, 16 (7.1%); warning, 5 (2.2%). In 2018, there was evidence of intervention to minimize the incident, 229 (24.5%); orientation, 208 (22.3%); and request to change the prescription, 77 (8.2%).

## Discussion

The study found limitations identified by the use of a secondary data source through handwritten notifications from the institution, where the quality and quantity of the information depend on the informant, directly impacting on the analysis of the findings and conclusions of the work. However, this research generated important information about the quality and safety of the patient at an organizational and assistance level, bringing to light challenges that require greater dedication from the management. Furthermore, it made it possible to identify that some goals have a small number of notifications, alerting to the need to investigate the occurrence of these incidents in the institution and, if they occur, whether they are being effectively notified.

Based on the findings of this study, it was identified that there was an increase in incident reporting, considering what was observed throughout the country. The researched institution has been developing a safety culture policy, aiming at health education in the scope of patient safety, with greater emphasis from the middle of 2017. It is believed that such behavior can demonstrate the maturity of professionals and safety policy culture<sup>(6-7)</sup>.

Given the low rate of notifications, the challenges of under-notification or even non-notification prevail, which can lead to the construction of false indicators, with real risk for decision making. Therefore, efforts to overcome this problem have been directed towards the development of computerized notification systems<sup>(7-8)</sup>.

After analyzing more than 1,089 handwritten and computerized notifications during a survey in a hospital institution, researchers concluded that computerized notifications are the most frequent to be performed in the daily practice of professionals, thus presenting themselves as more efficient<sup>(8)</sup>. The authors emphasize that the computerization of this practice favors the construction of a habit in which spontaneous reports are associated to a higher quality

of information, thus contributing to the improvement of the investigation process and evidence consolidation for decision making in favor of patient safety.

However, even in countries with more advanced reporting systems or in those where such action is mandatory, there is underreporting of incidents, focusing on the need to develop a safety culture among health care professionals, so that they feel encouraged to report errors that have occurred, understanding the importance of such action to improve the assistance provided<sup>(8-9)</sup>.

However, in several contexts, this daily practice is neglected, especially in long-term hospital environments, and mutual cooperation among health teams, users and managers is recommended in order to consolidate it as an efficient indicator, and no longer as a bureaucratic contribution in the organization<sup>(1-2)</sup>.

Regarding the effective communication, the data presented highlights for the lack of information among professionals, more than ostensibly highlight them as a problem in health environments, once they compromise since the formative process of those, prevailing as a great villain in the implementation of care. Thus, researchers<sup>(10-11)</sup> advocate that the development of continuous training focused on the development of professional ability to communicate assertively, with participative and meaningful approaches, such as realistic simulation, is essential to optimize the flow of information in the health sector.

Among the surveyed notifications, the occurrence of drug-related incidents was the most prevalent, similarly to another study<sup>(10-11)</sup>. It is estimated that each hospitalized patient is subject to one medication error per day, and notifications in the area of pharmacovigilance are the most frequent and may occur in several phases of the medication-use process<sup>(6)</sup>.

Regarding "Safe Surgery", incidents related to technical failures during procedures were highlighted, a reduced rate of events, since any failure in these assistance processes causes irreversible harm to patients. At this point, the occurrence or underreporting of the incidents found is questioned. A study found

the occurrence of 8.7% of surgical incidents, affirming the need for improvements in the management process of materials and human resources through permanent notification for screening and prevention of incidents<sup>(9)</sup>.

Notifications related to pressure injuries contemplate a reality that affects people of all age groups and results in significant financial burden to health systems, with increased investment in materials, equipment, drugs, surgical interventions and hospitalization time<sup>(12)</sup>. A low number of these reports related to pressure injuries can be observed in the researched institution, however the use of scales for measurement of this indicator is evidenced.

Regarding the incidents that were intercepted before reaching the patient, the highest rate was directed to the drug process, in the prescription and dispensing phase. A study that analyzed notifications of incidents related to potentially dangerous drugs obtained 1.1% dispensing error and 0.5% administration error, indicating the need for adopting strategies in order to ensure greater safety to the patient<sup>(13)</sup>.

In the incidents without harm in the researched universe, there was a prevalence of falls. Similar results were identified in another study that evidenced that 48.0% of the incidents without harm occurred as a result of errors followed by violations or failures in the system<sup>(14)</sup>. In this perspective, it is noteworthy that systems have varying safety degrees, which must be considered in their construction, operation and human limitations. The consequences for the patient can be classified according to the type of harm, degree and social and/or economic impact. In this study, the degree of mild damage was more frequent among adverse events and there was no record of notification that resulted in death.

Congruent to this, a study that described the incidents and adverse events reported in the emergency medical services of Asturias, Spain, found a total of 88.1% of the reported incidents, considered avoidable and 46.2% required some kind of intervention to mitigate the effects of the incident. The research also con-

cluded that notifications are an important source of information needed to understand the mistakes made and take measures to avoid them<sup>(15)</sup>. The importance of notification as an indicator for quality management in health services is emphasized.

Studies conducted in Spain and Finland have revealed that a cultural change is an important challenge and time-consuming hospital routine, which meets the proposed measures to minimize the effects of incidents. The educational practice, with stimuli to the notifications based on the non-punitive culture, contributes to a quality assistance, based on continuous improvement<sup>(5,15)</sup>. However, for these changes to be effective, it is necessary to review the work processes, besides capacitating and training these professionals, opening space to enable the installation of a safety culture. Furthermore, it becomes relevant that the institution makes available technologies for the improvement of care, collaborating for the prevention of incidents and their recurrence<sup>(8-11)</sup>.

## Conclusion

The data show that the type of incident most often was the potential damage. Therefore, in this general context, the incidents related to the use of drugs had more expressive numbers in relation to the others. It is evident that the culture of patient safety in the institution has shown signs of progressive maturity, however, efforts on the part of managers are still necessary, such as the implementation of institutional protocols and professional training to ensure safer health systems.

## Collaborations

Mascarello A and Massaroli A contributed to the conception and design, analysis and interpretation of the data, writing of the article and relevant critical review of the intellectual content. Pitilin EB, Araújo JS, Rodrigues ME and Souza JB contributed to the approval of the final version to be published.

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